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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,387	08/01/2003	Russell H. Barnes	13265	4140
7590 Battelle Memorial Institute 505 King Avenue Columbus, OH 43201-2693			EXAMINER LAMPRECHT, JOEL	
			ART UNIT 3737	PAPER NUMBER
			MAIL DATE 04/29/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/632,387

Applicant(s)

BARNES ET AL.

Examiner

JOEL M. LAMPRECHT

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/8/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19, 21, 27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 21, 27 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 7, 8, 9, 10, 14, 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu et al. (US 5,452,723). Wu et al disclose a method for diagnosing disease comprising generating data for Raman, fluorescence and diffuse reflectance spectra and images by direct optical measurement of tissue (in vivo or ex vivo) (Abstract, Col 1 Lines 25-45, Col 3 Lines 22-30, Claim 16), storing data as a library (Fig 15a/b and Fig 16a/b, Col 21 Lines 58- Col 22 Line 20), performing classification decisions to identify diseased or cancerous/precancerous tissues (Col 5 Line 15-30, (Col 3 Line 13-32, Col 23 Line 1-25), displaying images or data results to identify the state of tissues (Fig 13-16a/b), fusing data, and depth profiling as a function of time gating for profiling tissues (Col 6 Line 44-Col 7 Line 15 and Col 7 Line 28-35 for simulations to probe for depth profiling through Monte Carlo simulation). Col 6 Line 5 through Col 8 Line 55 disclose further measuring the area or volume in an unknown patient or using a known volume of tissue to calculate concentration and volume of tissue components in vivo (Col 1 Line 49-55). Wu et al. disclose an apparatus for identifying disease comprising sources of light for each of the desired spectra, multiple rotating mirror interfaces, tissue interface for illuminating tissue of a patient, image

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analysis modules for receiving light from a mirror interface with at least a non-imaging spectrometer with rotatable gratings, and system for taking diagnostic information according to diffuse reflectance and ultraviolet/visible light from the same initial beam alternatively (Col 4 Line 45 - Col 6 Line 35). Finally Wu et al. discloses an endoscope and fiber optic probe for the tissue interface (Figure 4, Clm 20, Col 6 Line 9-30) and discloses the use of the system and methods for cancer diagnosis (Claim 22).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14, 27 and 28 rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (US 5,452,723) in view of Kaneko (US 5,749,830) and in further view of Burgess et al. (Article attached). Wu et al disclose a method for diagnosing disease comprising generating data for Raman, fluorescence and diffuse reflectance spectra and images by direct optical measurement of tissue (in vivo or ex vivo) (Abstract, Col 1 Lines 25-45, Col 3 Lines 22-30, Claim 16), storing data as a library (Fig 15a/b and Fig 16a/b, Col 21 Lines 58- Col 22 Line 20), performing classification decisions to identify diseased tissues (Col 5 Line 15-30, (Col 3 Line 13-32, Col 23 Line 1-25), displaying images or data results to identify the state of tissues (Fig 13-16a/b), fusing data, and depth profiling as a function of time gating for profiling tissues (Col 6 Line 44-Col 7 Line

15 and Col 7 Line 28-35 for simulations to probe for depth profiling through Monte Carlo simulation). Wu et al. do not specifically provide time gating to reduce interferences between Raman and fluorescence measurements, although time gating and phase manipulations are mentioned, and does not provide specific fusing means for combining the spectral library of patient-specific data with the patient data. Attention is then directed to the secondary reference by Kaneko (US 5,749,830) in the same area of endeavor, which describes a method of fusing images and image data to provide for diagnosis of patient tissue from stored data in computer memory (Fig 6-7, 11 and Col 62 Line 28- Col 63 Line 7). Attention is also directed to the secondary reference by Burgess et al. which describes time gating as a means to reduce interferences from surface scattering and/or to reduce or remove interferences between Raman and fluorescence measurements (Abstract and Experimental Data Section 2). It would have been obvious to one having ordinary skill in the art at the time of the invention to have utilized the fusing and storage methods of Kaneko with the phase-gating methods taught by Burgess et al. in the method for diagnosing disease disclosed by Wu et al. to enable the best possible optical measurements and most accurate images for diagnosis.

Claims 15-19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (US 5,452,723) in view of Kaneko (US 5,749,830) and in further view of Malmros et al (US 2002/0058028 A1). Wu et al disclose a method for diagnosing disease comprising generating data for Raman, fluorescence and diffuse reflectance spectra and images by direct optical measurement of tissue (in vivo or ex vivo)

(Abstract, Col 1 Lines 25-45, Col 3 Lines 22-30, Claim 16), storing data as a library (Fig 15a/b and Fig 16a/b, Col 21 Lines 58- Col 22 Line 20), performing classification decisions to identify diseased tissues (Col 5 Line 15-30, (Col 3 Line 13-32, Col 23 Line 1-25), displaying images or data results to identify the state of tissues (Fig 13-16a/b), fusing data, and depth profiling as a function of time gating for profiling tissues (Col 6 Line 44-Col 7 Line 15 and Col 7 Line 28-35 for simulations to probe for depth profiling through Monte Carlo simulation). Wu et al. do not specifically provide time gating to reduce interferences between Raman and fluorescence measurements, although time gating and phase manipulations are mentioned, and does not provide specific fusing means for combining the spectral library of patient-specific data with the patient data. Attention is then directed to the secondary reference by Kaneko (US 5,749,830) in the same area of endeavor, which describes a method of fusing images and image data to provide for diagnosis of patient tissue from stored data in computer memory (Fig 6-7, 11 and Col 62 Line 28- Col 63 Line 7). Kaneko and Wu et al teach all that is listed above but fail to describe the use computer system which stores the database of spectra and images to compare them to another stored library of normal and diseased tissues. Attention is directed to the teaching reference by Malmros et al (US 2002/0058028 A1) which describes and claims the use of a spectral database on a computer for the purpose of comparing spectroscopy data for the purpose of diagnosing cancerous or non-cancerous tissues of a patient (Claims 1-6 0004, 0032, 0068 and 0070). It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the computer-based library-reference diagnosis methods of Malmros et al with the

methods and devices of Wu et al in view of Kaneko et al for the purpose of providing a computer-based diagnosis method for cancerous tissues (0065-0066, 0070).

Response to Arguments

Applicant's arguments filed 01/08/08 have been fully considered but they are not persuasive. Regarding the first argument that Wu et al does not disclose a library of spectral data for the purpose of allowing for comparison of data from said library to that of a patient for the purpose of diagnosis; Examiner respectfully disagrees. Wu et al discloses both the use of a patient data library and the use of simulation-data comparison for the purpose of diagnosing tissues. A procedure for data acquisition in order to provide a spectral library of data of some form capable of drawing conclusions about tissue properties is mentioned as above in the Wu disclosure (Figure 2, Fig 15a/b and Fig 16a/b, Col 21 Lines 58- Col 22 Line 20, and Col 5 line 15-37). The spectral data is made into an image as in Figures 15a/b and 16a/b and the disclosure integrates equations for both the removal of distortion and the diagnosis of tissue (Col 5 Line 15-37 and Col 23 Line 49-Col 24 Line 24). It would then be inherent that some pre-existing knowledge of the relationship of fluorophore presence and concentration could be relied upon based on the disclosure in column 5. If a data library stored on a computer system is the goal of the instant application, Examiner suggests that providing such a limitation would overcome the library of Wu et al currently being relied upon as a library of data where a library is a "collection of standard materials or formulations by which specimens are identified" (Dictionary.com, ref Biology definition) or "A collection of recorded data or tapes arranged for ease of use" (American Heritage), as is recited in

amended claim 15 (f). Regarding the argument that Wu does not provide 3 simultaneous measurement techniques, it is not a limitation of the claims as written that all 3 measurements must be taken simultaneously, only that those 3 measurements must be taken.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **JOEL M. LAMPRECHT** whose telephone number is (571)272-3250. The examiner can normally be reached on Monday-Friday 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L. Casler/
Supervisory Patent Examiner, Art
Unit 3737

JML